REMARKS

This amendment is in response to the non-final Official Action mailed on July 16, 2007. A two-month extension of the time to respond, up to and including December 16, 2007, is filed concurrently herewith. Entry of the foregoing and favorable reconsideration and reexamination of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, and in light of the remarks which follow, are respectfully requested.

Initially, applicant notes with appreciation the interview of October 4, 2007 and appreciates the Examiner's willingness to discuss the Official Action and art cited. As discussed during the interview, Applicant respectfully believes that the claims are distinguishable over the art cited. Applicant's respectfully submit that the response below is in line with the discussions of the interview.

By way of this response, claims 1, 4, 5, 13-20, and 22-28 are amended, new claims 29-31 have been added, claims 2, 3, 6-12, and 21 are canceled. Support for amended claims 1, 13, and 22 and new claims 29-31 can be found by reference to, for example, paragraphs [0030] to [0031]. No new matter has been added by way of the claim amendments.

In accordance with MPEP § 714(II)(B) and 37 C.F.R. § 1.125, submitted herewith is a substitute specification correcting various typographical errors in the specification. In addition to a clean version of the substitute specification ("CLEAN VERSION"), Applicant has also included a marked version of the specification ("MARKED VERSION") showing all the changes that have been made. The typographical errors that have been corrected include, for example, correction of "naxloxone" as used on page 4 at paragraph [0014] to read "naloxone." Similarly, the spelling of "opiod" has been changed to "opioid" throughout the specification. Pursuant to the Examiner's

request, references to trademarked pharmaceuticals have been denoted by the "®" symbol and have been capitalized. (*Office Action*, pages 2-3.) In addition, the generic or common chemical names of the pharmaceuticals have been added after the trademarked name, where appropriate, in lowercase. No new matter has been added by way of the amendments to the specification.

An amended Abstract is also included herein. This amendment merely corrects the spelling of the word "opioid." No new matter has been added by way of this amendment.

The Examiner objected to claims 18, 23, and 25 on informal grounds. (*Office Action*, page 3.) Applicants have amended these claims to correct a typographical error in the spelling of Trazodone as noted by the Examiner. Accordingly, this objection should be withdrawn.

The Examiner has rejected claims 1-5 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner believes that the "claims contain[] subject matter which was not disclosed in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention." (*Office Action*, pages 3-4.) Specifically, the Examiner objects to the broad language "opioid antagonists." Applicant has amended claim 1 to specify that the opioid antagonist is selected from the group consisting of naloxone and nalmefene HCl. Applicant further notes that original claim 13, which the Examiner did not reject under § 112, included similar language as amended claim 1. Accordingly, Applicant respectfully requests withdrawal of this rejection.

The Examiner has also rejected claims 4, 9, 13-16, 18, 22, 23, and 25-27 under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for failing to particularly point out

and distinctly claim the subject matter which applicant regards as the invention. (*Office Action*, page 5.) In accordance with the Examiner's recommendation, Applicant has amended the claims to replace any references to trademarked pharmaceutical products with the respective generic or common chemical names. Therefore, Applicant respectfully requests withdrawal of this rejection.

The Examiner has rejected claims 1-3 and 6-8 under 35 U.S.C. § 102(b) as allegedly being anticipated by *McDonald* (Journal of Neurosurgical Anesthesiology, April 2001). The Examiner believes that *McDonald* teaches all of the elements of the claimed invention, specifically the administration of an opioid antagonist at a rate of 50mg/hr. (*Office Action*, pages 5-6.) Applicant respectfully disagrees.

McDonald discloses "[o]pioid detoxification by infusion of 25mg [of] naloxone for 30 minutes, followed by a 24-hour infusion of 1mg per hour." (*McDonald*, page 74.) As such, *McDonald* teaches intravenous infusion at a certain rate over a specified period of time. (*McDonald*, page 75.) *McDonald* does not, however, teach bolus administration of an opioid antagonist, i.e. administration in a single dosage, as is recited in amended claims 1, 13 and 22. Moreover, the Examiner admits that *McDonald* "do[es] not teach the administration of naloxone in a single dosage." (*Office Action*, page 6.) Accordingly, *McDonald* does not anticipate the claimed invention and this rejection must be withdrawn.

The Examiner has also rejected claims 4, 5, 9, 10, 13, 14, and 17-18 under 35 U.S.C. § 103(a) as allegedly being unpatentable over *McDonald* in view of *Ibanez* (U.S. Patent No. 6,103,734), *Takrouri* (M.E.J. Anesth 16(6), 2002), and *Gooberman* (U.S. Patent No. 5,789,411). The Examiner contends that it "would have been obvious to one of ordinary skill in the art at the time the invention was made to administer naloxone in a

single dosage for the treatment of opiate addiction or detoxification." (*Office Action*, page 7.) The Examiner further contends that "[t]here is a reasonable expectation of successfully treating opiate detoxification with [a] 50mg single dosage of naloxone because the effectiveness of [a] 50mg daily dosage administration of naloxone is well taught by *McDonald*." (*Id.*) The Examiner relies on the secondary references to supply what is missing from *McDonald*, namely the administration of Precedex, anesthesia, antiemeitcs, etc. or intubation. (*Office Action*, pages 7-9.) Applicant respectfully traverses this rejection.

As already stated above, *McDonald* merely teaches infusion of naloxone over a period of 24 hours and does not disclose, or even suggest, that opioid antagonists may be administered as a single, bolus dose as in amended claims 1, 13, or 22. Nor do any of the secondary references provide that opioid antagonists can be administered as a bolus rather than an infusion over an extended period of time. In fact, *Takrouri* specifically teaches away from bolus administrations. *Takrouri*, page 588. "Because of its potency, [an opioid antagonist] can only be safely administered as an infusion (not a bolus)." (*Takrouri*, page 588 (emphasis added).) Similarly, *Ibanez* teaches administration over a period of time and dosages of naloxone that are much smaller than the claimed invention. (*See, for example, Ibanez*, claim 13.) Indeed, the references reflect the conventional wisdom of the art to date and expressly teach away from the subject matter of claims 1, 13 and 22. As stated in paragraph [0010] of the specification, giving more than 4 mg in a single dose was not recommended.

In view of the foregoing, Applicant respectfully submits that the Examiner's line of reasoning and art of record does not support rejection of the claims. In fact, the art relied on by the Examiner reflects that conventional wisdom to

this day that an opioid antagonist can only be safely administered as an infusion. In fact, the Examiner has not provided any evidence that a single, relatively large dosage of an opioid antagonist would effectively detoxify a patient with any predictable results. Accordingly, one skilled in the art would not be motivated by the teachings of McDonald, alone or in combination with the secondary references, to administer a bolus of opioid antagonist as in the claimed invention. As such, the rejection should be withdrawn.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited. If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that she telephone Applicant's attorney at (908) 654-5000 in order to overcome any additional objections which she might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: December 7, 2007

Respectfully submitted,

By_____
Orville R. Cockings
Registration No.: 42,424
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicant

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